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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,397	03/09/2004	Robert Falotico	CRD-5068	1881

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
BERRIOS, JENNIFER A	

ART UNIT	PAPER NUMBER
1619	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,397	FALOTICO ET AL.	
	Examiner	Art Unit	
	Jennifer A. Berríos	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, filed 2/24/2009, with respect to Claims 2-5 have been fully considered and are persuasive, as the above claims were cancelled. The rejections therefore are withdrawn.

2. The terminal disclaimer filed on 2/24/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of co-pending application 10/883,328 has been reviewed and is accepted. The terminal disclaimer has been recorded. As such the rejection of claims 1-3 and 6-11 in the grounds of nonstatutory double patenting over claim 3 of co-pending application 10/833328 in view of Fischell has been withdrawn.

3. Applicant's arguments, filed 2/24/2009, with respect to the rejection(s) of claim(s) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn.

a. Claims1-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borges et al. (US 2005/0033417 A1) in view of Fischell et al. (US 2003/0065382 A1).

b. Claims 1-3, 6, 7, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. (US 2002/0123801 A1) in view of Fischell et al. (US 2003/0065382 A1).

However, upon further consideration, a new ground(s) of rejection are made.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 1 and 6-11 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recited "the topotecan being present in a concentration of about 75 **nanometers** to about 300 **nanometers**." It is well known to those in the art that concentration is not measured in length. After looking through the instant specification, Examiner is interpreting the claims to read nanomolar (nm) instead of nanometer.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borges et al (US 2005/0033417), Fischell et al (Us 2003/0065382), Eury et al (Us 2002/0004679) and Shull et al (WO 96/34003).

Borges teaches coating an implantable medical device with a composition comprising a basecoat and a topcoat, wherein the basecoat includes at least one active agent that is incorporated into a first polymeric material, the basecoat is affixed to the surface of the medical device, and the topcoat contains a second polymeric material which is affixed to the basecoat for the purpose of controlling the elution rate of the at least one active agent (paragraph [0027]). Borges teaches a particular embodiment where the basecoat comprises a fluoropolymer and rapamycin and the topcoat comprises an acrylic polymer (paragraph [0030]). Borges also teaches the particular

medical devices, stents, anastomosis devices and stent-grafts (abstract; paragraph [0032]). Borges further discusses drug combination therapy mainly for the treatment of restenosis and lists possible drugs that may be employed in the invention including rapamycin, cladribine and etoposide (paragraphs [0085]-[0087]).

Regarding claims 9-11, instant claims 9 requires the second polymeric material (an acrylic) to be incompatible with the first polymeric material (fluoropolymer), thereby creating both a physical and a chemical barrier to the elution of rapamycin and the topoisomerase inhibitor. The examiner takes the position that since Borges teaches a stent comprising a basecoat with a fluoropolymer and rapamycin and a topcoat comprising an acrylic, the creation of a chemical/physical barrier is an expected property of the stent of Borges, as the polymeric material is identical to the polymeric material in instant claims 10 and 11.

Borges is silent to the particular drug combination of rapamycin and a topoisomerase I inhibitor, specifically topotecan with a concentration of 75-100 nm.

Fischell teaches a stent that is coated with a composition comprising a polymer and one or more anti-restenosis drugs selected from the group consisting of a finite amount of particular drugs including topoisomerase I inhibitors including adriamycin etoposide, irinotecan and hycamptin (topotecan) as well as rapamycin (abstract; paragraphs [0020] and [0022]).

Eury teaches the use of topoisomerase inhibitors for the prevention of restenosis. The method includes administering a topoisomerase inhibitor on a stent for local administration (Abstract). The topoisomerase inhibitor is selected from camptothecin,

irinotecan and topotecan. In one embodiment the polymer stent is loaded with camptothecin, irinotecan or topotecan (Pg 1 [0015]). A second active agent can be co-administered with the topoisomerase inhibitor, such as Paclitaxel (Pg 1 [0017]), well known to those of ordinary skill in the art to aid in the prevention of restenosis (Pg 2 [0022]).

One of ordinary skill in the art would have been motivated to include any combination of the finite number of anti-restenosis drugs suggested by Fischell because they are all art-recognized equivalents used for the same purpose. All references teach coating an implantable medical device with a composition comprising anti-restenosis drugs, thus one skilled in the art would readily look to Fischell for other anti-restenosis drugs or combinations of anti-restenosis drugs. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as a topoisomerase I inhibitor, specifically topotecan, camptothecin or irinotecan as taught by Eury, and a rapamycin. Thus, in Borges, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular anti-restenosis drug combination of a rapamycin and a topoisomerase I inhibitor such as irinotecan or topotecan as suggested by Eury and Fischell.

11. Borges/Fischell/Eury fail to teach the specific concentration of topotecan recited. Shull teaches chemotherapeutic agents, such as camptothecin, being delivered in vivo to fight cancer growth in the body. For in vivo cell inhibition assays, camptothecin was found to have the following 50% cell growth inhibition concentration (Table 4) ranging

from 5.74 nm to about 3223.7nm depending on the cell line, It would have been prima facie obvious to one of skill in the art at the time the invention was made utilize topotecan in the concentrations taught by Shull dependent on the desired results. One of ordinary skill in the art would have been motivated to do so because topotecan and camptothecin are art-recognized equivalents, both topoisomerase I inhibitors, useful on polymeric stents for the treatment of restenosis, furthermore it would have been obvious to vary the concentration of topotecan used depending on the cell line looking to inhibit as Shull teaches that different cell lines require different concentration to achieve 50% inhibition.

Conclusion

No claims are allowable.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Berríos whose telephone number is (571)270-7679. The examiner can normally be reached on Monday-Thursday: 7:00am-4:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JB

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615